

02-06-2007 12:30

From: Ruden McClosky

5618323036

T-738 P.002/016 F-826

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Application of PATTERSON, Stacey

Application No.: 10/697,419 Examiner: Iqbal Hossain Chowdhury


Date filed: October 30, 2003 Art Unit: 1652

Attorney Docket No.: 6704-30 Confirmation No.: 7565

For: MODIFIED LUCIFERASE NUCLEIC ACIDS AND METHODS OF US

CERTIFICATE UNDER 37 CFR 1.8(A)

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Alexandria, VA, 22313-1450 on February 6, 2007.


Reg. No. 42,730
Stanley A. Kim, Ph.D., Esq.

Mail Stop - REFUND
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

On January 25, 2007 our deposit account no. 50-3110 was charged \$350.00 under Fee Code 2202 (claims in excess of twenty), equivalent to fourteen (14) additional claims in the above-identified patent application. We believe this fee to have been charged incorrectly, as payment for all extra claims had already been processed. Details are as follows:

The instant application, including 26 claims, was filed on October 30, 2003, at which time the Commissioner had been authorized to charge the fee (\$54.00) for the six additional claims to deposit account no. 50-0951. A preliminary amendment, introducing seven (7) additional claims, was filed on January 26, 2005. Again, the Commissioner had been authorized to charge the extra claim fee (\$175.00) to deposit account no. 50-3110 (different deposit account number, due to change in Power of Attorney). This charge,

WFB:281341:1

PAGE 2/16 * RCVD AT 2/6/2007 12:30:41 PM [Eastern Standard Time] * SVR:USPTO-EFXXF-5/13 * DNS:2736500 * CSID:5618323036 * DURATION (mm-ss):04-12

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T-739 P.003/016 F-826

Patent Application No.: 10/697,419
Refund Request
February 6, 2007

Docket No. 6704-30

however, was not deducted from our deposit account until September 11, 2006. No additional claims were introduced to the application in amendments filed on September 19, 2006 and January 11, 2007, respectively. Consequently, at no time were there more than a total of 33 claims pending in the application. To further substantiate our claim, enclosed herewith are copies of:

- The fee transmittal of the application as originally filed;
- The preliminary amendment filed on January 26, 2005, including an authorization to the Commissioner to charge deposit account no. 50-3110 for any fees due (page 9);
- Deposit account statement for September of 2006, reflecting a charge in the amount of \$175.00 on September 11, 2006; and
- Deposit account statement for January of 2007, reflecting a charge in the amount of \$350.00;

In view of the above, a refund in the amount of \$350.00 to deposit account no. 50-3110 is requested.

Date: 2/6/07

Respectfully Submitted,

SA Kim
Stanley A. Kim, Ph.D., Esq.
Registration No. 42,730
RUDEN, McCLOSKEY, SMITH
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WPB:281341:1

02-06-2007 12:30

From: Ruden McClosky

5618323036

T-739 P.004/016 F-826

PATENT
Docket No. 6704-30

PATENT APPLICATION TRANSMITTAL LETTER

Commissioner for Patents
MAIL STOP PATENT APPLICATION
P.O. Box 1450
Alexandria, VA 22313-1450

Transmitted herewith for filing of the patent application of:

Inventors: Stacey PATTERSON
Rakesh GUPTA
Gary SAYLER
Hebe DIONISI

For: MODIFIED LUCIFERASE NUCLEIC ACIDS AND METHODS OF USE

Enclosed are:

- ☒ Specification, including the Abstract
- ☒ 3 Sheets of drawings
- ☒ Unexecuted Declaration and Power of Attorney
- ☒ Sequence Listing in Computer readable form and (paper copy)
- ☒ Statement Under 37 C.F.R. 1.821(f)
- ☒ Other: 2 postcards

CLAIMS AS FILED

FOR	NO. FILED	NO. EXTRA
Basic Fee		
Total Claims	-26-	-6-
Indep Claims	-3-	-0-
multiple dependent claim present No		

If the difference in Col. 1 is less than zero, enter "0" in Col. 2

Small Entity

RATE	FEE
	\$ 385.00
x \$ 9 =	\$ 54.00
x \$ 43 =	\$
x \$ 145 =	\$
TOTAL	\$ 439.00

Other than a Small Entity

RATE	FEE
	\$ 750
x \$ 18 =	\$
x \$ 84 =	\$
x \$ 250 =	\$
TOTAL	\$

- ☒ Please charge my Deposit Account No. 50-0951 in the amount of \$439.00
- ☒ Applicant(s) Claims Small Entity Status
- ☒ A check in the amount of \$_____ is enclosed.
- ☒ The Commissioner is hereby authorized to charge any under or credit any overpayment to Deposit Account No. 50-0951. A duplicate of this sheet is enclosed.
- ☒ Any additional filing fees required under 37 C.F.R. 1.16.
- ☒ Any patent application processing fees under 37 C.F.R. 1.17.
- ☐ Fee enclosed.

Date

Amy A. Ostrom
Amy A. Ostrom, Ph.D.
Registration No. 52,088

(WP156295:1)

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PAGE 4/16 * RCVD AT 2/6/2007 12:30:41 PM [Eastern Standard Time] * SVR:USPTO-EFAXF-5/13 * DNIS:2736500 * CSID:5618323036 * DURATION (mm-ss):04-12

02-06-2007 12:31

From: Ruden McClosky

5618323036

T-739 P.005/018 F-826

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: PATTERSON, et al.

Application No.: 10/697,419

Examiner:

Date Filed: October 30, 2003

Group: 1645

For: MODIFIED LUCIFERASE NUCLEIC ACIDS AND METHODS OF USE

CERTIFICATE UNDER 37 CFR 1.9(a)

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as First Class mail in an envelope addressed to the Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450, on January 26, 2007

Amy A. Ostrom Reg. No. 52,088
Amy A. Ostrom, Ph.D.

PRELIMINARY AMENDMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Prior to examination, please amend the above-identified application as follows:

Amendments to the Claims begin on page 2 of this paper.

Remarks begin on page 9 of this paper.

WPB:193623:1

1

Amendments to the Claims

The following listing of the claims will replace all prior versions and listings of claims in the application:

Listing of Claims:

Claim 1 (currently amended): A nucleic acid comprising a codon-optimized nucleotide sequence encoding at least one [a] component of a bacterial luciferase system selected from the group consisting of a bacterial LuxA protein and a bacterial LuxB protein.

Claim 2 (currently amended): The nucleic acid of claim 1, wherein the codon-optimized nucleotide sequence differs from a wild type nucleotide sequence that encodes the at least one component of a bacterial luciferase system by at least one codon substitution selected from the group consisting of: TTT to TTC; TTA, CTA, TTG, and CTT to CTG or CTC; ATT and ATA to ATC; GTT and GTA to GTG or GTC; TCT, TCA, and TCG to TCC; CCA and CCG to CCC or CCT; ACT, ACA and ACG to ACC; GCA and GCG to GCT or GCC; TAT to TAC; CAT to CAC; CAA to CAG; AAT to AAC; AAA to AAG; GAT to GAC; GAA to GAG; TGT to TGC; CGT and CGA to CGC, CGG, and AGA; AGT to AGC; and GGT and GGA to GGC or GGG.

Claim 3 (currently amended): The nucleic acid of claim 1, wherein the at least one component of a bacterial luciferase system comprises a LuxA polypeptide.

Claim 4 (original): The nucleic acid of claim 3, wherein the codon-optimized nucleotide sequence is SEQ ID NO:1.

Claim 5 (currently amended): The nucleic acid of claim 1, wherein the at least one component of a bacterial luciferase system comprises a LuxB polypeptide.

Claim 6 (original): The nucleic acid of claim 5, wherein the codon-optimized nucleotide sequence is SEQ ID NO:2.

Claim 7 (original): The nucleic acid of claim 1, further comprising a regulatory element operably linked to the codon-optimized nucleotide sequence.

Claim 8 (original): The nucleic acid of claim 7, wherein the regulatory element comprises an enhancer.

Claim 9 (currently amended): A cell comprising a nucleic acid comprising a codon-optimized nucleotide sequence encoding at least one [a] component of a bacterial luciferase system selected from the group consisting of a bacterial LuxA protein and a bacterial LuxB protein.

Claim 10 (original): The cell of claim 9; wherein the cell is a mammalian cell.

Claim 11 (original): The cell of claim 9, wherein the cell is immobilized on a substrate.

Claim 12 (currently amended): The cell of claim 9, wherein the codon-optimized nucleotide sequence differs from a wild type nucleotide sequence that encodes the at least one

component of a bacterial luciferase system by at least one codon substitution selected from the group consisting of: TTT to TTC; TTA, CTA, TTG, and CTT to CTG or CTC; ATT and ATA to ATC; GTT and GTA to GTG or GTC; TCT, TCA, and TCG to TCC; CCA and CCG to CCC or CCT; ACT, ACA and ACG to ACC; GCA and GCG to GCT or GCC; TAT to TAC; CAT to CAC; CAA to CAG; AAT to AAC; AAA to AAG; GAT to GAC; GAA to GAG; TGT to TGC; CGT and CGA to CGC, CGG, and AGA; AGT to AGC; and GGT and GGA to GGC or GGG.

Claim 13 (currently amended): The cell of claim 9, wherein the at least one component of a bacterial luciferase system comprises a LuxA polypeptide.

Claim 14 (original): The cell of claim 13, wherein the codon-optimized nucleotide sequence is SEQ ID NO:1.

Claim 15 (currently amended): The cell of claim 9, wherein the at least one component of a bacterial luciferase system comprises a LuxB polypeptide.

Claim 16 (original): The cell of claim 15, wherein the codon-optimized nucleotide sequence is SEQ ID NO:2.

Claim 17 (original): The cell of claim 9, wherein the codon-optimized nucleotide sequence is operably linked to a regulatory element.

Claim 18 (original): The cell of claim 17, wherein the regulatory element comprises an enhancer.

Claim 19 (currently amended): A method comprising the step of introducing into a mammalian cell a nucleic acid comprising a codon-optimized nucleotide-sequence encoding at least one [a] component of a bacterial luciferase system selected from the group consisting of a bacterial LuxA protein and a bacterial LuxB protein.

Claim 20 (currently amended): The method of claim 19, wherein the codon-optimized nucleotide sequence differs from a wild type nucleotide sequence that encodes the at least one component of a bacterial luciferase system by at least one codon substitution selected from the group consisting of: TTT to TTC; TTA, CTA, TTG, and CTT to CTG or CTC; ATT and ATA to ATC; QTT and GTA to GTG or GTC; TCT, TCA, and TCG to TCC; CCA and CCG to CCC or CCT; ACT, ACA and ACG to ACC; GCA and GCG to GCT or GCC; TAT to TAC; CAT to CAC; CAA to CAG; AAT to AAC; AAA to AAG; GAT to GAC; GAA to GAG; TGT to TGC; CGT and CGA to CGC, CGG, and AGA; AGT to AGC; and GGT and GGA to GGC or GGG.

Claim 21 (currently amended): The method of claim 19, wherein the at least one component of a bacterial luciferase system comprises a LuxA polypeptide.

Claim 22 (original): The method of claim 21, wherein the codon-optimized nucleotide sequence is SEQ ID NO:1.

Claim 23 (currently amended): The method of claim 19, wherein the at least one component of a bacterial luciferase system comprises a LuxB polypeptide.

Claim 24 (original): The method of claim 23, wherein the codon-optimized nucleotide sequence is SEQ ID NO:2.

Claim 25 (original): The method of claim 19, wherein the codon-optimized nucleotide sequence is operably linked to a regulatory element.

Claim 26 (original): The method of claim 25, wherein the regulatory element comprises an enhancer.

Claim 27 (new): A nucleic acid made by the steps of:

(a) providing a polynucleotide encoding at least one luciferase component selected from the group consisting of a bacterial LuxA protein and a bacterial LuxB protein; and

(b) making in the polynucleotide at least one codon substitution selected from the group consisting of: TTT to TTC; TTA, CTA, TTG, and CTT to CTG or CTC; ATT and ATA to ATC; GTT and GTA to GTG or GTC; TCT, TCA, and TCG to TCC; CCA and CCG to CCC or CCT; ACT, ACA and ACG to ACC; GCA and GCG to GCT or GCC; TAT to TAC; CAT to CAC; CAA to CAG; AAT to AAC; AAA to AAG; GAT to GAC; GAA to GAG; TGT to TGC; CGT and CGA to CGC, CGG, and AGA; AGT to AGC; and GGT and GGA to GGC or GGG,

wherein the resulting codon-substituted nucleic acid is expressed at higher levels when placed in a mammalian cell under expression-promoting conditions than is the polynucleotide of step (a) when placed in the mammalian cell under the expression-promoting conditions.

Claim 28 (new): The nucleic acid of claim 27, wherein the at least one luciferase component comprises a bacterial LuxA protein.

Claim 29 (new): The nucleic acid of claim 27, wherein the at least one luciferase component comprises a bacterial LuxB protein.

Claim 30 (new): The nucleic acid of claim 27, wherein the at least one luciferase component comprises both a bacterial LuxA protein and a bacterial LuxB protein.

Claim 31 (new): A kit for analyzing gene expression, the kit comprising:

- (a) a vector comprising
 - (i) a nucleic acid of claim 1 or claim 27;
 - (ii) at least one restriction site;
 - (iii) at least one promoter;
 - (iv) at least one selection marker; and
 - (v) at least one initiation site; and
- (b) instructions for use.

Claim 32 (new): The kit of claim 31, wherein the vector further comprises an IRES.

02-06-2007 12:32 From:Ruden McClosky

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T-739 P.012/016 F-826

Claim 33 (new): The kit of claim 31, wherein the vector further comprises an enhancer.

WPB:193623:1

8

REMARKS

Status of the Application

Claims 1-26 were originally submitted with the application as filed. Claims 1-3, 5, 9, 12, 13, 15, 19-21, and 23 have been amended herein and support for the amendments can be found in the original specification as filed (See e.g., lines 26-29, page 2). New claims 27-33 have been added herein and are also supported throughout the original specification as filed. For example, the subject matter of independent claims 27 and 31 finds support in Example 2 at pages 15-27 of the specification.

By this amendment, claims 1-3, 5, 9, 12, 13, 15, 19-21, and 23 have been amended and new claims 27-33 have been added. Therefore, claims 1-33 are now before the examiner for consideration.

Conclusion:

The currently pending claims are supported throughout the specification and are patentable over the prior art. No new matter has been added. Allowance of the application is respectfully requested.

The Commissioner is hereby authorized to charge any fee for the newly added claims and any underpayment or credit any overpayment of fees under 37 CFR 1.16 or 1.17 as required by this paper to Deposit Account 50-3110.

The examiner is invited to call the undersigned if clarification is needed on any matter within this amendment, or if the examiner believes a telephone interview would expedite the prosecution of the subject application to completion.

02-06-2007 12:32

From-Ruden McClosky

5618323036


T-739 P.014/016 F-826

Respectfully submitted,

RUDEN, MCCLOSKEY, SMITH,
SCHUSTER & RUSSELL, P.A.

Dated: January 26, 2007

Docket No: 6704-30


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10

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T-738 P.015/018 F-826



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09/08	5	PCT/US06/24074	52728-0068	1802	-\$1,000.00	\$17,735.00
09/08	6	PCT/US06/24074	62728-0066	1603	\$300.00	\$17,435.00
09/11	2	10697419	6704-30	2201	\$100.00	\$17,335.00
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09/13	8	11508661	52728-0059	8021	\$40.00	\$17,120.00
09/18	152	11521020	52728-0099	2011	\$150.00	\$16,970.00
09/18	153	11521020	52728-0099	2111	\$250.00	\$16,720.00
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09/20	144	60846364	55798-0002	2005	\$100.00	\$18,030.00
09/25	129	29237382	53790-0001	2502	\$400.00	\$17,630.00
09/26	130	29237382	53790-0001	8001	\$30.00	\$17,600.00

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**TRANSMITTAL
FORM**

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Total Number of Pages in This Submission 16

Application Number	10/697,419
Filing Date	October 30, 2003
First Named Inventor	PATTERSON, Stacy
Art Unit	1652
Examiner Name	Isabel Hossain Chowdhury
Attorney Docket Number	6704-30

ENCLOSURES (Check all that apply)

- ☐ Fee Transmittal Form
- ☐ Fee Attached
- ☐ Amendment/Reply
- ☐ After Final
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- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Reply to Missing Parts/Incomplete Application
- ☐ Reply to Missing Parts under 37 CFR 1.52 or 1.53

- ☐ Drawing(s)
- ☐ Licensing-related Papers
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- ☐ Status Letter
- ☐ Other Enclosure(s) (please identify below):
- Fee Transmittal of original application
 - Prel. Amendment filed on 1/26/05
 - Deposit account statement Sept. 2006
 - Deposit account statement Jan. 2

Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name Ruden, McClosky, Smith, Schuster & Russell, P.A.

Signature

Printed name Stanley A. Kim, Ph.D., Esq.

Date February 6, 2007

Reg. No. 42,730

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Typed or printed name Stanley A. Kim, Ph.D., Esq.

Date February 6, 2007

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